

Claims:

1. A pharmaceutical aqueous suspension comprising:

a) a therapeutically effective amount of suspended solid particles comprising at least one active ingredient;

b) a thickener;

c) a nucleation inhibitor; and

d) at least one amino polycarboxylic acid compound; and

wherein the suspension has a pH of about 3.7 to 8.

2. A suspension according to claim 1, wherein the suspended solid particles are hydrophobic and the suspension further comprises a surfactant.

3. A suspension according to claim 1, wherein the suspended solid particles have a median particle size, as measured by laser scattering, of about 1 to about 20 microns.

4. A suspension according to claim 1, wherein the suspension comprises a blend of at least a structuring agent and a swelling agent as the thickener.

5. A suspension according to claim 1, wherein the active ingredient is substantially insoluble in an aqueous environment at room temperature.

6. A suspension according to claim 1 wherein the aqueous suspension has a pH between 3 and 6 at room temperature.

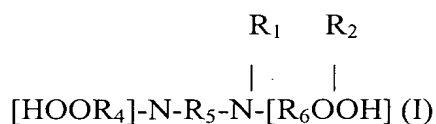
7. A suspension according to claim 1 wherein the nucleation inhibitor is polyvinylpyrrolidone.

8. A suspension according to claim 1 wherein the pH of the aqueous suspension remains within 0.2 pH units for a period of at least four weeks starting from its complete formulation when stored at a temperature of at least 60°C.

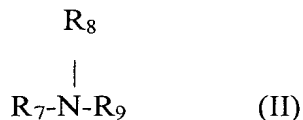
9. A suspension according to claim 1 wherein the viscosity remains constant for at least two weeks when stored at a temperature of at least 60°C.

10. A suspension according to claim 1 wherein the viscosity within a range of plus or minus 25% of its initial value for a period of at least 8 weeks when stored at a temperature of 60°C.

11. A suspension according to claim 1 wherein the amino polycarboxylic acid compound is a compound according to formula (I) and pharmaceutically acceptable salts thereof:



wherein R₁ and R₂, independently of one another, are hydrogen, hydroxy-terminated C₁-C₄ alkylene, carboxylic-terminated C₁-C₄ alkylene or N-[R₃OOH]_m; and R₃, R₄, R₅ and R₆ are independently of one another are C₁-C₄ alkylene and m is 1 or 2; or formula (II)



wherein R₇, R₈ and R₉, independently of one another, are hydrogen, C₁-C₄ alkyl, carboxylic-terminated C₁-C₄ alkylene or hydroxy-terminated C₁-C₄ alkylene and pharmaceutically acceptable salts of formula (I) or (II).

12. A suspension according to claim 11, wherein at least one amino polycarboxylic acid compound is represented by formula (I) and R₁, R₂ and R₃ are ethylene.

5 13. A suspension according to claim 1, wherein the amino polycarboxylic acid compound is selected from the group consisting of ethylenediaminetetraacetic acid (EDTA), hydroxyethylethylenediaminetriacetic acid, dihydroxyethylethylenediaminediacetic acid, 1,3-propanediaminetetraacetic acid, diethylenetriaminepentaacetic acid, triethylenetetraminehexaacetic acid,
10 iminodiacetic acid, methyliminodiacetic acid, nitrilotriacetic acid, and salts thereof, and mixtures thereof.

14. A suspension according to claim 1, wherein the amino polycarboxylic acid compound is selected from ethylenediaminetetraacetic acid and salts thereof and
15 mixtures thereof.

15. A suspension according to claim 1, wherein the amino polycarboxylic acid compound is disodium ethylenediaminetetraacetate.

20 16. A suspension according to claim 11 wherein the active ingredient is an anti-histamine or analgesic.

17. A suspension according to claim 14 wherein the active ingredient is loratadine.

25 18. A suspension according to claim 16 wherein the active ingredient is acetaminophen or ibuprofen.

19. A pharmaceutical aqueous suspension comprising:

a) a therapeutically effective amount of suspended solid particles comprising at least one active ingredient;

b) a blended thickening component, said thickening component comprising a swelling agent and a structuring agent;

5 c) at least one amino polycarboxylic acid compound; and
wherein the suspension has a pH of about 3.7 to 8.

20. A suspension according to claim 19 wherein the swelling agent is a pregelatinized starch and the structuring agent is a hydrocolloid.

21. A suspension according to claim 19 further comprising a surfactant.

22. A pharmaceutical aqueous suspension comprising a therapeutically effective amount of suspended solid particles comprising at least one active ingredient
15 selected from the group consisting of fexofenadine, loratadine, desloratadine, terfenadine, astemizole, norastemizole, cetirizine, and pharmaceutically acceptable salts, esters, isomers, and mixtures thereof,
wherein the suspension has a pH of about 3.7 to 8; and
wherein the suspended solid particles have a median particle size, as measured by
20 laser scattering, of about 1 to about 20 microns after 4 weeks at 60°C.